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August 7, 2025

The Honorable Richard G. Andrews
United States District Court
for the District of Delaware
844 N. King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 23-975-RGA

Dear Judge Andrews:

We write in response to the letter filed by Liquidia regarding its NDA and the form of the Court's forthcoming judgment. *See* D.I. 440.

Should UTC prevail on infringement and validity for at least one claim, UTC is entitled to the remedy prescribed by 35 U.S.C. § 271(e)(4)(A). That statute provides mandatory relief requiring FDA to set the approval date to no earlier than the expiration of the '327 patent. That the mandatory relief may impact Liquidia's PAH indication is a result of Liquidia's regulatory strategy, which involved seeking approval for PAH and PH-ILD in the same application.

Liquidia chose that strategy knowingly and intended to launch at risk for PH-ILD from the outset. Indeed, Liquidia hurried to amend its NDA to add a PH-ILD indication before the '327 patent issued to avoid a 30-month stay. *See* PTX242.00002; Trial Tr. 56:22-57:17. Liquidia initially intended to seek approval for PH-ILD via a supplemental NDA (sNDA) after PAH approval, but later changed course and amended its existing Yutrepia NDA after the USPTO issued a Notice of Allowance on the '327 patent. *Id.*; PTX-0377.00003-04.

FDA will be required to implement the Court's mandatory § 271(e)(4)(A) order. How FDA acts in response to any subsequent submission from Liquidia will be up to FDA. But Liquidia is not entitled to advance notice from the Court about the Court's ruling. Liquidia can react after the Court's ruling, as it deems appropriate. If necessary, the small number of patients with expiring Yutrepia prescriptions can use the UTC dry powder formulation, which has been safely and effectively treating PH-ILD patients since approval in May 2022. Trial Tr. 6:18-21, 33:24-34:1.

UTC understands that this Court's typical practice—including with these parties in a prior case—has been to address potential remedies *after* a decision has been issued. There is no reason to depart from this practice here. Liquidia's citation to "UTC's claims for damages" and implicit request to discuss damages is similarly premature. *See* D.I. 380, Final Pretrial Conf. Tr. at 68:4-12.

Liquidia's proposed carve-out strategy also fails to fully address the problems with its at-risk launch. This approach omits important safety information and does nothing to undo the marketing for PH-ILD that Liquidia has already done and is actively doing now. Further, the Federal Circuit recently affirmed this Court's ruling that a § 271(e)(4)(A) order must be directed to the *infringing drug application itself*, not an infringing indication contained therein, because it is the submission of the application that constitutes infringement under § 271(e)(2). *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1068 (Fed. Cir. 2024). If, as here, the application recites a non-infringing indication, this cannot "negate the infringement resulting from [the application's] submission." *Id.*

Finally, Liquidia's citation to UTC's Statement of Intended Proofs in the Pretrial Order (D.I. 335, Ex. 17 at ¶ 25) is incomplete and misleading. UTC has been clear throughout this case, including in post-trial briefing, that while Liquidia's infringement of the Asserted Claims is due to its PH-ILD indication, any resulting § 271(e)(4)(A) order must be directed to Liquidia's Yutrepia NDA, not just the PH-ILD indication. *See, e.g.*, D.I. 8 at 18; D.I. 334, Ex. 4 ¶ 68; D.I. 431 at 70. UTC's statement in the Pretrial Order is not to the contrary.

For these reasons, UTC does not believe advance vetting with the Court of Liquidia's *potential* but not-yet-taken approach is appropriate or that a status conference is necessary, but UTC counsel will be available at the Court's convenience if it desires to set one.

Respectfully submitted,

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Counsel for Plaintiff United Therapeutics Corporation

cc: Clerk of Court (by hand delivery)
All Counsel of Record (by e-mail)